



Consumer Consent for Health Information Exchange: An Exploration of Options for Arizona's HIEs

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Introduction

The rise of Health Information Exchanges (HIEs)¹ across the country is an exciting development that promises to improve the quality of care, increase the efficiency of health care services by making health information available at the point of care for every patient, and empower consumers by making information about their care more available to them. Of course, the development of HIEs also poses real challenges in how to structure HIEs to ensure that consumer information is available to providers and consumers for those purposes, yet ensure rigorous health information confidentiality protections are in place.

This White Paper discusses one other fundamental policy challenge that every HIE must make in establishing its operations: whether and how to seek consumer consent to exchange a consumer's health information through the HIE. As this White Paper explores in detail, this is a difficult issue to resolve because different stakeholders in the health care community – consumers, health care providers, HIE administrators and others – often have different and sometimes strongly held beliefs about this issue. In addition, decisions about consumer consent will have an impact on the way an HIE's technology is structured, and some of those decisions may be too difficult or expensive to implement.

The consumer consent issue is a complicated policy decision that should be made only after a thorough consideration of all the issues involved, and by balancing the needs of the participants in the system. This White Paper presents a discussion on the options available to HIEs.

What issues will affect the decision on consumer consent to exchange health information through an HIE?

The policy decision of whether and when to seek consumers' consent to exchange health information through the HIE is a nuanced decision that depends on many interrelated factors:

- Do state laws or regulations require consumer consent to exchange health information? If so, in what circumstances?
- What type of information will be submitted through the HIE? Does any of the health information exchanged require additional protection, such as substance abuse treatment information?
- Who will access the exchange? For example, is access limited to health care providers or will health plans and others also have access?
- For what purposes is the HIE used? Will it be limited to treatment purposes, or are other uses of the health information contemplated?
- Can consumers trust that the HIE is secure?
- Is there accountability in the event someone inappropriately uses the exchange?

If the answer to any one of these questions changes, it may alter the policy decision about whether and how consumer consent would be sought. For example, if an HIE is used only by health care providers for treatment purposes, the decision on consumer consent may be different than if the HIE is used by health plans for payment purposes. It's three dimensional policy chess!

What do different stakeholders think about the consent issue?

It is important to keep in mind that a person's membership in a certain category of stakeholder does not dictate that person's ideas about consumer consent. So, this discussion will obviously contain generalizations that may not ring true to specific individuals.

Consumers: Not surprisingly, consumers appear to hold varied attitudes about whether they should have the ability to consent before their health information is exchanged via an HIE. Consumers who have chronic care needs, or who have children who have serious illnesses or

disabilities, often express tremendous support for HIE in order to facilitate communication between different parts of the care team and to avoid the need to be the coordinator for the information. These consumers are primarily concerned with the immediate availability of their health information to health care providers and may not support the need to get up-front consent if it will interfere with or slow down the transmission of their health information.

Other consumers are primarily concerned about their privacy, particularly if they have received care for conditions they feel would be stigmatizing or could lead to the denial of insurance coverage. For example, the organization Patient Privacy Rights is a strong advocate of the right to consent in advance of transmission of health information, even to providers for treatment purposes.

Both perspectives are completely legitimate, of course, and there are many individuals and organizations that fall somewhere between these perspectives. Ultimately, an individual's approach to consent depends on an individual's particular life circumstances and experiences.

Health care providers: Health care providers also have varied opinions on this subject. Many are, not surprisingly, primarily concerned with ensuring that they have complete information available about a patient at the time they provide care. In New Hampshire, for example, the legislature is considering a bill (HB 1587) that would allow patients to block provider access to information in electronic health records and in HIEs; hospitals, physicians, nursing homes and other providers have opposed the legislation because they believe it would compromise their ability to get complete information.

Other health care providers, particularly physicians who are involved in providing mental health care or treatment for other sensitive conditions, are extremely concerned that the lack of consumer consent

to exchange health information will discourage some individuals from obtaining care at all.

HIE administrators: Individuals involved in creating and running HIEs are concerned with ensuring that the HIE is valuable to their communities. They want to provide a robust service to participating health care providers, and so must respond to the needs of those providers. They also are concerned about the cost of building and maintaining the HIE so that the HIE can be an ongoing service to the community.

Of course, health care providers and HIE administrators are also consumers of health care. Anyone involved in making a policy decision on the consent issue should keep that health care consumer "hat" firmly in place.

What does Arizona law require?

Arizona law does not require consumer consent to exchange health information for treatment purposes. Arizona law also generally does not require consumer consent for providers to exchange health information for a variety of other purposes, such as getting paid for the treatment they provide, for various business functions called "health care operations" (such as quality assurance activities), for public health purposes, and for research where an Institutional Review Board has reviewed the research and approved doing the research without consent (if there is sufficient privacy protection in place).

This analysis starts with the general medical records law for providers in Arizona,² which states that providers may follow the Health Insurance Portability and Accountability Act (HIPAA) regulations³ in their disclosures of health information. HIPAA permits disclosures for treatment, payment, "health care operations" (general business activities, such as quality assurance), public health purposes, and research, without consumer consent or authorization.

We then look to determine whether any of the health information being exchanged is “special” health information that is subject to any greater restrictions. Arizona law has special statutes for genetic testing information,⁴ mental health information held by licensed behavioral health providers,⁵ and HIV and communicable disease information.⁶ All of this information may be disclosed for treatment purposes without consumer consent. This information may also be disclosed for some public health purposes and research where an Institutional Review Board has reviewed the research and approved a waiver of consent. And except for genetic testing information, health care providers may also exchange this health information for payment and “health care operations” without advance consent.

For health care providers that are federally-assisted substance abuse treatment programs, however, the federal regulations on substance abuse treatment information set additional restrictions on the exchange of health information without consumer consent, even for treatment purposes. These restrictions are substantial, so any HIE should exclude information that comes from these providers.

In summary, Arizona law does not require advance consumer consent to exchange information through an HIE for most purposes. It is therefore a *policy* decision on whether consumer consent will be required to exchange health information through an HIE, and for what purpose. A complete explanation of these Arizona and federal laws is included in the Arizona Health-e Connection Briefing Paper at pages 25-29 and 44-53, which can be found on the Arizona Health-e Connection website (www.azhec.org) in the “About AzHeC” section.

What are the options for Arizona HIEs?

Generally, there are four options for HIEs to consider in making the decision about whether and how consumers consent to the electronic exchange of health information:

- **Option 1- Opt In**
Seek advance consent from consumers to include their health information in an HIE;
- **Option 2- Opt Out**
Provide consumers the right to “opt out” of having their health information in an HIE;
- **Option 3- Notice Only**
Include all consumers’ health information in an HIE, with notice to or education of consumers about the process; or
- **Option 4- Combination**
Take a blended approach, employing Options 1-3 as appropriate, depending on the particular uses of information and who has access to the HIE.

HIEs are coming to very different decisions on this issue and are fairly evenly split across the country. Whichever approach is chosen, it should be transparent to consumers through extensive public education!

Option 1: Opt In

Seek advance consent from consumers to include their health information in an HIE. What are the advantages and disadvantages, and how would it work?

Advantages:

Consumer control: Consumers have a very legitimate interest in controlling their health information. Ideally, each consumer would have the right to determine who could see his or her health information and determine the purpose for which that health information is used.

Risk management for the HIE: From the HIE perspective, seeking advance consent could serve a risk management function. The consent form would educate individuals about how health information is exchanged, who will have access to it, and what consumer rights are vis-à-vis the HIE and the participants in the HIE. This proactive education through the consent process could

reduce liability to an HIE in the event a participant misuses the exchange.

Enabling better patient record matching: If the process of seeking advance consent is done through an in-person process, that consent process could eventually support the collection of biometric identifiers, such as fingerprints. These biometric identifiers would permit accurate patient record matching by the HIE – two individuals may have the same names (and sometimes even same birthdates), but they don’t have the same fingerprints. At this time, biometric identifiers are not commonly used. Patient access to their own information in an HIE could also assist in increasing the accuracy of records in the system.

Disadvantages:

Delay in getting information to providers for treatment: The primary disadvantage of the opt-in process is that the need to obtain advance consent from a consumer to exchange health information could delay the transmission of that information to providers. Consumers may not have the opportunity to consent before their information is needed, particularly in an emergency.

Less support from physicians: Another substantial disadvantage of the opt-in process is that seeking advance consent to include health information in the exchange may not garner support by physicians and other health care providers for two reasons. First, physicians consistently report that if an exchange does not have complete information on their patients, physicians will not view the exchange as reliable. For liability purposes, physicians want as complete information as possible and may not rely on a source of information from which their patients could withhold information. Second, physicians may not be willing to work an HIE into their office workflow if the information is not complete. In Massachusetts, for example, the Massachusetts Health Data Consortium reportedly discontinued its MedsInfo-ED project because the project could not collect

certain medication information without advance patient consent. When physicians consistently found the project did not contain medication information about the patient presenting for care, the physicians stopped using the MedsInfo-ED database.

Granularity of consent: Next, the “granularity” of consent is problematic. Will the HIE seek all-or-nothing consent? In other words, will consumers be forced to make a decision between including all of their information in the exchange or none of it? Or will they be able to consent to the sharing of specific pieces of information? How will this process work?

Expense and administrative burden. The final disadvantage is that an opt-in process would be expensive to support, and may create unwelcome bureaucracy for consumers. In administering a consent process, the following operational issues may be challenging to implement:

- Who will seek the consent? Health care providers may be tasked with seeking consent from their patients, as providers’ face-to-face interactions with patients will facilitate the consent process and give them the chance to explain how the HIE works. However, some providers may object to the time that would be required to explain HIE participation to their patients, to fill out the necessary paperwork, and to transmit that paperwork to the appropriate entities.
- Will one consent be sufficient for a consumer to participate in the system as a whole, or will it be necessary for each provider to seek consent from that provider’s patients? If the latter, how will this work?
- How will a consumer’s consent to participate be communicated to the HIE? To other providers?
- What will the process be for revoking consent? How will revocation affect

information already in the HIE? How will revocation be communicated to others?

Option 2: Opt Out

Provide consumers the right to “opt out” of having their health information in an HIE. What are its advantages and disadvantages, and how would it work?

Advantages:

Consumer control. As discussed above, consumers have a very legitimate interest in controlling who sees their health information and to determine the purpose for which that health information is used. Under an opt-out system, consumers would be required to contact an HIE (or their health care providers) to be removed from the system, but that still would provide a level of control to consumers.

As the National Committee on Vital and Health Statistics noted in a February 2008 report, “where individuals have the right to put restrictions on disclosure of sensitive health information, people rarely elect to do so, but they strongly value having the right and ability to do so.”⁷ The Indiana Network for Patient Care (INPC), administered by the Regenstrief Institute and one of the longest operating HIEs in the country, had an opt-out system for many years; a representative of the INPC reported that very few individuals opted out of its system.

Disadvantages:

Granularity of opt-out: As with the “opt-in” option, the “granularity” of the opt-out is problematic. Will the HIE require an all-or-nothing opt-out? Will it be specific to the type of use? To the type of information? To who will access the information? The HIE architecture will have a substantial affect on the consent management options.

Expense and administrative burden: The final disadvantage is that an opt-out process may be administratively difficult to support. In administering the opt-out process, the following operational issues may be challenging:

- Who will collect consumer opt-outs? If health care providers are tasked with collecting opt-outs for their patients, they may object to the time that may be required to explain participation to their patients, to fill out the necessary paperwork, and to transmit that paperwork to the appropriate entities.
- If opt-outs are collected at the provider level, will the opt-out be effective only for that provider? Or will the opt-out apply to the entire system and be effective with regard to all providers’ information?
- How will a consumer’s opt-out be communicated to the HIE? To other providers?
- What will the process be for a consumer to change his or her decision and later participate in the system?
- How will subsequent opt-outs be handled? Will a later opt-out affect information already in the HIE? How will the opt-out be communicated to others?

Option 3: Notice Only

Include all consumers’ health information in an HIE, with notice to or education of consumers. What are its advantages and disadvantages, and how would it work?

Advantage:

More flexibility for coordination with other HIEs and response to developing technology. Because multiple HIEs are developing in Arizona, it is important to ensure consistency among HIE policies to permit them to exchange health information with each other. The “early on the scene” HIEs may decide to adopt option 3 to facilitate coordination with other HIE policies. (If an early HIE chooses to implement an opt-in or opt-out process, it may be more difficult them to roll out an alternative policy later.) Moreover, HIE consent management technology is evolving, which hopefully will allow in the

future more granular control by consumers to sequester certain types of sensitive health information.

Results in most useful HIE: An HIE that includes all available patient information—subject to stringent privacy and security protections—is the most valuable for health care providers. When health care providers know they can rely on an HIE to provide complete information on their patients, health care providers will trust the HIE as a source of valuable information and will integrate access to the HIE into their workflows. An exchange that contains complete patient information also will be extremely valuable for public health purposes (such as bioterrorism surveillance across multiple records) and research, if those uses are approved by HIE policy decision makers.

Easy to administer: Because option 3 does not have an opt-in or opt-out process to implement, the HIE will be easier to administer. Particularly while HIEs are struggling with methods to finance the delivery of this important service, that is a significant consideration.

Of course, providing notice to consumers does entail some costs and implementation questions such as:

- How will notice be provided to consumers? Will it be provided by the HIE to the public at large? Will providers participating in the HIE be required to provide notice to their patients?
- If notice is provided by health care providers, will the HIE develop common content for all providers to use?
- How will notice be coordinated with other HIEs, particularly to support exchange between HIEs?

These costs are substantially less than in Options 1 or 2.

Disadvantages:

Less consumer control: As discussed above, consumers have a legitimate concern with deciding who may see their health information and for what purpose. While e-health exchange will essentially function as an electronic version of the types of exchanges that happen in health care in paper form today, it is possible that some consumers will be more concerned now that the exchanges will occur electronically. Consumers with sensitive conditions may decide not to provide complete information when receiving care in order to keep that sensitive information out of the HIE.

Option 4: Combination

Take a blended approach, employing Options 1-3 as appropriate. What are its advantages and disadvantages, and how would it work?

Some HIEs are discussing taking a “blended” approach—including all available information in the exchange, but providing different levels of consumer control based on the use of the information. For example, an HIE may permit access by providers to information for treatment purposes without advance consumer consent, but implement an opt-in or opt-out process for other uses of information, such as for research.

Once the technology is available, an HIE could also implement a varied approach to different types of health information and for particular individuals. For example, the HIE could implement a policy of requiring affirmative opt-in for a particular provider to see substance abuse treatment information (which now would be excluded from the HIE). As consent management tools and HIE technology advance, more granularity will be possible.

Conclusion

HIEs across the country are struggling with the issue how to implement consumer consent for e-health information exchange,

because it is a complicated and many-faceted issue.

The federal government is also considering what type of consent is appropriate for the National Health Information Network (NHIN)—the effort to connect HIEs across the country. The National Committee on Vital and Health Statistics (NCVHS), a federal advisory body that advises the Department of Health and Human Services (HHS) on health data, statistics and national health information policy, issued a report on February 20, 2008, in which the NCVHS recommended that the Secretary of HHS implement a policy for the NHIN to allow individuals to “have limited control, in a uniform manner, over the disclosure of certain sensitive health information for purposes of treatment.”⁸ NCVHS expressed concern about “protecting patients’ legitimate concerns about privacy and confidentiality, fostering trust and encouraging participation in the NHIN in order to promote opportunities to improve patient care, and protecting the integrity of the health care system.” NCVHS thus recommended the development—through an open public process—to uniformly decide across the country which categories of health information (such as information related to domestic violence, genetic information, mental health information, reproductive health, and substance abuse) an individual would be permitted to sequester from access in the NHIN without express consent for a particular provider or in an emergency.

At the same time, the NCVHS recognized “that the technologies and human factors needed to implement the recommendations in this letter are not necessary readily available for the EHR systems, HIEs, and other components of the emerging NHIN.” This is a situation where HIE architecture and available technology may have to catch up with desired policy outcomes.

Moreover, Arizona has the challenge of coordinating the policy decisions on consent across the state as multiple HIE networks

develop throughout the state. How will the consent process be coordinated across HIEs? For example, if one HIE implements the opt-in consent option, but another implements the notice-only option, how will these HIEs be able to exchange patient information? Arizona must carefully avoid the creation of information silos, because that will not benefit consumers.

Clearly, as we move forward in developing HIEs across Arizona, we need to initiate an open and transparent dialog—involving a wide range of interested stakeholders—about consumer consent for exchange of health information. A good policy outcome will balance the needs of consumers, health care providers and HIEs, taking into account our state laws, consumer concerns about privacy and security of health information, and technological capabilities for HIE architecture. With this open and transparent dialog, we will make electronic health information exchange a reality in Arizona.

¹ A word about terminology in this White Paper: the term “Health Information Exchange,” like “Regional Health Information Organization,” refers to the entity that is facilitating or conducting the exchange of health information.

² A.R.S. § 12-2291, *et seq.*

³ 45 C.F.R. Part 160 and Part 164, Subpart E (the HIPAA Privacy Rule).

⁴ A.R.S. § 12-2801, *et seq.* and § 20-448.02, *et seq.*

⁵ A.R.S. § 36-501, *et seq.*

⁶ A.R.S. § 36-661, *et seq.* and § 20.448.01.

⁷ <http://www.ncvhs.hhs.gov/080220lt.pdf>.

⁸ *Id.*